

## CLAIMS

1. A botanical drug or dietary supplement, for the treatment of or for use in patients with Hepatitis C infection, consisting essentially of botanical raw materials, botanical drug substances or botanical ingredients from each:
  - (a) The fruit of *Silybum marianum*;
  - (b) The root of *Astragalus membranaceus* var mongholicus or *Hedysarum polybotrys*;
  - (c) The root of *Salvia miltiorrhiza*, *Salvia bowleyana* or *Salvia przewalskii*; and
  - (d) The fruit of *Schisandra chinensis* or *Schisandra sphenanthera*.
2. A botanical drug or dietary supplement as claimed in claim 1 wherein each species is present in an amount, relative to the total weight of all of the botanical raw materials, botanical drug substances or botanical ingredients, as follows:
  - a) *Silybum* spp. from 22-48%;
  - b) *Astragalus* spp. or *Hedysarum* spp. from 20-63%;
  - c) *Salvia* spp. from 13-48%; and
  - d) *Schisandra* spp. from 2-19%.
3. A botanical drug or dietary supplement as claimed in claim 2 wherein each species is present in an amount as follows:
  - (a) *Silybum* spp. from 30-40%;
  - (b) *Astragalus* or *Hedysarum* spp. from 20-30%;
  - (c) *Salvia* spp. from 20-30%; and
  - (d) *Schisandra* spp. from 7.5-15%.
4. A botanical drug or dietary supplement as claimed in claim 2 or 3 wherein each species is present in an amount as follows:
  - (a) *Silybum* spp. 35.3% plus or minus 10%;
  - (b) *Astragalus* or *Hedysarum* spp. 26.5% plus or minus 10%;
  - (c) *Salvia* spp. 26.5% plus or minus 10%; and
  - (d) *Schisandra* spp. 11.7% plus or minus 10%.
5. A botanical drug as claimed in any of the preceding claims which consists essentially of botanical drug substances.
6. A botanical drug as claimed in claim 5 further comprising excipients.
7. A botanical drug as claimed in claim 5 wherein the botanical drug substances comprise total extracts derived from each of the botanical raw materials.

8. A botanical drug as claimed in claim 5 wherein the botanical drug substances comprise one or more defined extract fractions derived from each of the botanical raw materials.
- 9 A botanical drug as claimed in any of claims 5 to 8 in which the botanical drug substances are standardised extracts.
10. A botanical drug as claimed in claim 9 wherein the botanical drug substance from the *Silybum* spp. is standardised against a marker of silybin.
11. A botanical drug as claimed in claim 9 wherein the botanical drug substance from the *Silybum* spp. comprises at least 30% by weight silybin and isosilybin when calculated by HPLC method.
12. A botanical drug as claimed in any of claims 9 to 11 wherein the standardised extract of the *Silybum* spp. is a brownish yellow powder which is or has:
  - (i) no less than 30% silybin by HPLC;
  - (ii) no more than 0.5% soluble in pentane;
  - (iii) a sulphated ash content of no more than 1%;
  - (iv) a heavy metal content of no more than 100ppm;
  - (v) a residual organic solvent content of no more than 1% ethanol, no more than 0.01% ethyl acetate and no more than 0.01% hexane;
  - (vi) a bacterial content of no more than 1000 cfu/g; and
  - (vii) a fungal content of no more than 100cfu/g.
13. A botanical drug as claimed in claim 9 wherein the botanical drug substance from the *Astragalus* spp. is standardised against a marker of Astragaloside IV.
14. A botanical drug as claimed in claim 13 wherein the botanical drug substance from the *Astragalus* spp. comprises at least 0.4% by (weight) Astragaloside IV as calculated by HPLC method.
15. A botanical drug as claimed in either claim 13 or 14 wherein the botanical drug substance from the *Astragalus* spp. has a TLC chromatographic fingerprint substantially as illustrated in Fig 1 or a HPLC fingerprint substantially as illustrated in Fig 4.
16. A botanical drug as claimed in any of claims 13 to 15 wherein the standardised extract of *Astragalus* spp. is a pale yellow powder which is or has:
  - (i) no less than 0.4% Astragaloside IV;
  - (ii) a total ash content of no more than 5%;

- iii) an acid insoluble ash content of no more than 2%; and
  - iv) a microbial total viable aerobic count of no more than of 1000 cfu/g.
17. A botanical drug as claimed in claim 9 wherein the botanical drug substance from the *Salvia* spp. is standardised against a marker of Tanshinone II A.
18. A botanical drug as claimed in claim 17 wherein the botanical drug substance from the *Salvia* spp. comprises at least 1.5% by (weight) of Tanshinone IIA as calculated by HPLC method
19. A botanical drug as claimed in either claim 17 or 18 wherein the botanical drug substance from the *Salvia* spp. has a TLC chromatographic fingerprint substantially as illustrated in Fig 2 or a HPLC fingerprint substantially as illustrated in Fig 6.
20. A botanical drug as claimed in any of claims 17 to 19 wherein the standardised extract of the *Salvia* spp. is a dark red powder which is or has:
- (i) no less than 1.5% Tanshinone IIA by HPLC;
  - (ii) a total ash content of no more than 5%;
  - iii) an acid insoluble ash content of no more than 2%; and
  - iv) a microbial total viable aerobic count of no more than of 1000 cfu/g.
21. A botanical drug as claimed in claim 9 wherein botanical drug substance from the *Schisandra* spp. is standardised against a marker of Schizandrol A.
22. A botanical drug as claimed in claim 21 wherein the botanical drug substance from the *Schisandra* spp. comprises at least 2.0% by weight Schizandrol A by HPLC method.
23. A botanical drug substance, as claimed in either claim 21 or 22 wherein the botanical drug substance from the *Schisandra* spp. has a TLC chromatographic fingerprint substantially as illustrated in Fig 3 or a HPLC fingerprint substantially as illustrated in Fig 8.
24. A botanical drug substance as claimed in either claim 22 or 23 wherein the standardised extract of *Schisandra* spp. is a brownish red powder which is or has:
- (i) no less than 2.0 % Schizandrol A;
  - (ii) a total ash content of no more than 5%;
  - iii) an acid insoluble ash content of no more than 2%; and
  - iv) a microbial total viable aerobic count of no more than of 1000 cfu/g.
25. A botanical drug as claimed in any of claims 9 – 24 wherein each standardised extract is a dried ethanolic extract.

26. A botanical drug as claimed in any of claims 9 – 25 wherein the *Silybum* spp. is extracted according to a process substantially as illustrated in Fig 10.
27. A botanical drug as claimed in any of claims 9 – 25 wherein the *Astragalus* spp. is extracted according to a process substantially as illustrated in Fig 11.
28. A botanical drug as claimed in any of claims 9 – 25 wherein the: *Salvia* spp. is extracted according to a process substantially as illustrated in Fig 12.
29. A botanical drug as claimed in any of claims 9 – 25 wherein the *Schisandra* spp. is extracted according to the process substantially as illustrated in Fig 13..
30. A botanical drug as claimed in any of claims 9 – 29 which is provided in a unit dosage form.
31. A botanical drug as claimed in claims 30 which is a suspension powder mixture.
32. A botanical drug as claimed in claims 31 further comprising as excipients:
  - a) one or more gellants or thickeners comprising at least one xanthum gum having a particle size distribution such that 100% by weight of the particles pass a 60 mesh sieve, 95% by weight of the particles pass a 80 mesh sieve and 70% by weight of the particles pass a 200 mesh sieve,
  - b) one or more fillers; and
  - c) one or more wetting agents and or surfactants.
33. A botanical drug as claimed in claims 32 wherein the xanthan gum has a molecular weight of from  $3.5$  to  $4.0 \times 10^6$ .
34. A botanical drug as claimed in claims 32 wherein the wetting agent is a polyethylene glycol or macrogol.
35. A botanical drug as claimed in any of claims 30 to 34 further comprising one or more of a disintegrating agent, a lubricant, a sweetening agent, a flavouring agent and a viscosifying agent.
36. A botanical drug as claimed in any of claims 30 to 35 which is packaged in a sachet.
37. A botanical drug as claimed in any of claims 30 to 36 which is packaged with a dispensing container.
38. A botanical drug as claimed in claim 37 wherein the dispensing container has a sealable lid.
39. A botanical drug as claimed in any of claims 9 to 38 comprising in a unit dose:
  - i) 0.200g to 0.250g of a botanical drug substance from a *Silybum* spp. (equivalent to 12g to 15g of botanical raw material);

- ii) 0.585g to 1.95g of a botanical drug substance from a *Astragalus* spp. (equivalent to 9g to 30g of botanical raw material) ;
- iii) 0.225g to 0.375g of a botanical drug substance from a *Salvia* spp. (equivalent to 9g to 15g of botanical raw material) and
- iv) 0.150g to 0.600g of a botanical drug substance from a *Schisandra* spp. (equivalent to 1.5g to 6g of botanical raw material).

40. A method of treating a patient to reduce or alleviate the symptoms of Hepatitis, particularly Hepatitis C, or to support healthy liver function comprising administering to a patient a botanical drug or dietary supplement as claimed in any of claims 1-4 or a botanical drug as claimed in any of claims 5 to 39.

41. The use of a botanical drug or dietary supplement as claimed in any of claims 1- 4 or a botanical drug as claimed in any of claims 5 to 39 in combination with another drug to reduce or alleviate the symptoms of Hepatitis, particularly Hepatitis C, or to support healthy liver function.

42. The use as claimed in claim 41 wherein the another drug is interferon.

43. A botanical drug or dietary supplement, for the treatment of or for use in patients with Hepatitis C infection, comprising botanical raw materials, botanical drug substances or botanical ingredients from each of:

- (a) The fruit of *Silybum marianum*;
- (b) The root of *Astragalus membranaceus* var mongholicus or *Hedysarum polybotrys*;
- (c) The root of *Salvia miltiorrhiza*, *Salvia bowleyana* or *Salvia przewalskii*; and
- (d) The fruit of *Schisandra chinensis* or *Schisandra sphenanthera*

in an amount by weight relative to the total weight of the botanical raw materials, botanical drug substances or botanical ingredients as follows:

- (a) *Silybum* spp. no less than 22%
- (b) *Astragalus* or *Hedysarum* spp. no less than 20% ;
- (c) *Salvia* spp. no less than 13%; and
- (d) *Schisandra* spp. no less than 2% .

44. A botanical drug or dietary supplement as claimed in claim 43 in which each species is present in an amount by weight relative to the total weight of the botanical raw materials, botanical drug substances or botanical ingredients as follows:

- (a) *Silybum* spp. no less than 22%
- (b) *Astragalus* or *Hedysarum* spp. no less than 20% ;
- (c) *Salvia* spp. no less than 13%; and
- (d) *Schisandra* spp. no less than 2%